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BIOLOGICAL FLUID SAMPLING DEVICE**CROSS-REFERENCE TO RELATED APPLICATION**

The present application claims priority to U.S. Provisional Application No. 61/811,918, filed Apr. 15, 2013, entitled "Medical Device for Collection of a Biological Sample", the entire disclosure of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION**1. Field of the Disclosure**

The present disclosure relates generally to devices, assemblies, and systems adapted for use with vascular access devices. More particularly, the present disclosure relates to devices, assemblies, and systems adapted for collecting biological samples for use in point-of-care testing.

2. Description of the Related Art

Blood sampling is a common health care procedure involving the withdrawal of at least a drop of blood from a patient. Blood samples are commonly taken from hospitalized, home-care, and emergency room patients either by finger stick, heel stick, or venipuncture. Blood samples may also be taken from patients by venous or arterial lines. Once collected, blood samples may be analyzed to obtain medically useful information including chemical composition, hematology, or coagulation, for example.

Blood tests determine the physiological and biochemical states of the patient, such as disease, mineral content, drug effectiveness, and organ function. Blood tests may be performed in a clinical laboratory or at the point-of-care near the patient. One example of point-of-care blood testing is the routine testing of a patient's blood glucose levels which involves the extraction of blood via a finger stick and the mechanical collection of blood into a diagnostic cartridge. Thereafter, the diagnostic cartridge analyzes the blood sample and provides the clinician a reading of the patient's blood glucose level. Other devices are available which analyze blood gas electrolyte levels, lithium levels, and ionized calcium levels. Some other point-of-care devices identify markers for acute coronary syndrome (ACS) and deep vein thrombosis/pulmonary embolism (DVT/PE).

Despite the rapid advancement in point-of-care testing and diagnostics, blood sampling techniques have remained relatively unchanged. Blood samples are frequently drawn using hypodermic needles or vacuum tubes attached to a proximal end of a needle or a catheter assembly. In some instances, clinicians collect blood from a catheter assembly using a needle and syringe that is inserted into the catheter to withdraw blood from a patient through the inserted catheter. These procedures utilize needles and vacuum tubes as intermediate devices from which the collected blood sample is typically withdrawn prior to testing. These processes are thus device intensive, utilizing multiple devices in the process of obtaining, preparing, and testing blood samples. Each additional device increases the time and cost of the testing process.

Point-of-care testing devices allow for a blood sample to be tested without needing to send the blood sample to a lab for analysis. Thus, it is desirable to create a device that provides an easy, safe, reproducible, and accurate process with a point-of-care testing system.

SUMMARY OF THE INVENTION

The present disclosure provides a biological fluid sampling device adapted to receive a blood sample and includes a

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housing having a reservoir disposed therein and a first cavity in fluid communication with the reservoir. The biological fluid sampling device of the present disclosure incorporates the concepts of lancing, blood collection, and multiple test strip collection. The biological fluid sampling device includes a first test element removably receivable within the first cavity and a lancet having a puncturing element. Additionally, the housing may include a second cavity in fluid communication with the reservoir and a second test element removably receivable within the second cavity. With the blood sample received within the reservoir of the biological fluid sampling device, the first test element and the second test element are adapted to receive a portion of the blood sample. In this manner, the biological fluid sampling device allows for a blood sample to be collected on a plurality of test elements simultaneously. For example, the biological fluid sampling device allows for only a single stick on a patient and collection of a blood sample into multiple test strips for a point-of-care testing device. In one embodiment, a portion of the biological fluid sampling device contains a sample stabilizer to promote efficient mixing with the blood sample. The sample stabilizer can be an anticoagulant, or a substance designed to preserve a specific element within the blood such as, for example, RNA, protein analyte, or other element.

In accordance with an embodiment of the present invention, a biological fluid sampling device includes a housing having an inlet port, a reservoir disposed within the housing and in fluid communication with the inlet port, and a first cavity in fluid communication with the reservoir. The device also includes a first test element removably receivable within the first cavity, and a puncturing element, a portion of which is disposed within the housing and adapted for movement between a pre-actuated position wherein the puncturing element is retained within the housing, and a puncturing position wherein the puncturing element extends through the inlet port of the housing.

In certain configurations, the biological fluid sampling device is adapted to receive a blood sample. The housing may include an upper portion and a lower portion, with the inlet port provided within the lower portion. The device may also include an adhesive disposed on a bottom surface of the lower portion. The reservoir may be adapted to receive the blood sample via the inlet port. The upper portion may be a resiliently deformable member and the upper portion may be transitionable between an undeformed position and a deformed position. Actuation of the upper portion from the undeformed position to the deformed position may move the puncturing element from the pre-actuated position to the puncturing position. After the puncturing element moves to the puncturing position, the upper portion returns to its undeformed position and returns the puncturing element to the pre-actuated position. When the blood sample is received within the reservoir, the first test element is adapted to receive a portion of the blood sample.

In additional configurations, the housing also includes a second cavity in fluid communication with the reservoir. A second test element may be removably receivable within the second cavity. The device may also include a check valve in the upper portion. Optionally, a first portion of the housing may include a first sample stabilizer. A second portion of the housing may also include a second sample stabilizer.

In accordance with another embodiment of the present invention, a biological fluid sampling device includes a housing having an inlet port, a reservoir disposed within the housing and in fluid communication with the inlet port, a first cavity in fluid communication with the reservoir, and a second cavity in fluid communication with the reservoir. The